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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/814,527

03/30/2004

Alpern Robert

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58415 7590 06/24/2009  
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EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

06/24/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,527	<b>Applicant(s)</b> ROBERT ET AL.	
	<b>Examiner</b> NEIL LEVY	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-11,13-15,36 -49,51,60 - 76 is/are pending in the application.
- 4a) Of the above claim(s) 5-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,13-15,36-49,51,60-71-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,3 and 5-11,13-15,36 -49,51,60 - 76 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/10/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 3, 5-11, stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/2/07.

### ***Claim Rejections - 35 USC § 112***

Claim 1, 13-15, 36—49, 51, 60-71, 73, 75 & 76 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering a crosslinked homopolymer of the instant claim 1, having the in vivo binding capacity of 4 mmol or more, to subjects with compromised kidney function, does not reasonably provide a basis for identification of an effective amount, for a given species, age, sex, of the now claimed polymers, in the open guise, to give, for any period of time, to any human or specific animal with any of the claimed diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to Practice the invention commensurate in scope with these claims.

The in vivo binding capacity of 4 mmol or more required should be re-inserted in claim 1, & new claim 62, while the polymers should be identified, as crosslinked & homopolymers.

***Claim Rejections - 35 USC § 103***

Claims 1, 13-15, 36-44, 60-76 stand rejected under 35 U.S.C. 103(a) as being unpatentable over MARTANI EP 039453 IN VIEW OF MURUGESAN et al

US005846990A & NOTENBOMER EP 0730494

MARTANI utilizes eudrajit polymers with added actives. As they travel through the GI tract, and release active, the carboxylic moieties of the eudrajit polymer would be free to bind Na, at the same positions of the GI tract and to the same degree, as would administration of the instant polymers. However, MARTANI discusses the oral

formulations, but not the disease states. Those are shown by MURUGESAN, with associated drugs, to be administered, orally, in any suitable manner to humans and animals (column 8, lines 38-46), thus, inclusive of bound to polymers taught by MARTANI.

The same moieties are seen on the NOTENBONER polymer, and they do in fact lower sodium ion levels and water in human and animals (column 4, lines 1-9) when applied in food, feed, drinks, or pharmaceutical compositions.

Martani, applicant's arguments notwithstanding shows a laxative, glycerin (examples 2,3) with acrylic acid & polystyrene sulfonate acid resins, for oral administration to patients in pain, regardless of their disease (p.3, lines 9-18). Since

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these dosages are oral, they would remove Na as they pass through the G.I. tract, since these are the instant polymers.

MURUGESAN further shows the instant syndromes for which the instant drugs (claim 43) are suitable , & thus treatment regimens of MARTANI would be obvious to incorporate with useful drugs of MURUGESAN (col. 7).

Notenbomer discloses a particle formulation comprising a cation exchange resin with the claimed moieties, able to bind sodium ions (page 3, lines 3-20). Page 3, lines 8-12 teaches that the particles encapsulate the ions and remove them through the GI tract. Page 3, lines 20-34 discloses examples of the cation exchange material such as polyacrylates. Page 4, lines 1-2 teach that the particles of the invention are good for lowering Na, thus supporting administration of these polymers would result in reducing Na load in a patient in need thereof.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize a Na binding polymer to use one of MARATANI modified with MURUGESAN & Notenbomer drugs, in order to provide acceptable application and improve the status of a patient in need thereof.

There is no unobvious and/or unexpected results obtained since the prior art is well aware of the use of cation exchange polymers for enhancement and the use of ingredients for the functionality for which they are known to be used is not a basis for patentability.

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As amended The polymers are not specified as homopolymers, nor are the in vivo binding capacity of 4 mmol or more required, while crosslinked polymers are also not required, & the prior art thus can be seen as evident to the artisan to achieve the instant claimed Na removal.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed.

### ***Response to Arguments***

Applicant's arguments filed 6/10/09 have been fully considered but they are not persuasive. Applicant has removed a critical factor from the claims, & thus the open language permits of the understanding of the resins & polymers needed for Na binding as shown in the prior art.

We concur with the evaluation of applicant's attorney on the double patenting issue, & that rejection is withdrawn (over now US 7488495). If there are remaining co-pending or patented cases subject to double patenting consideration, they should be brought to examiner's attention.

claims remaining Withdrawn will be considered upon re-insertion of the binding capacity & clarification & distinction of the polymers as cross linked, & homopolymers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM EST..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/  
Primary Examiner, Art Unit 1615

6/18/09